

*H.B.*  
SMALL BUSINESS

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS  
(37 C.F.R. 1.9(f) AND 1.27(c)) - SMALL BUSINESS CONCERN**

I hereby declare that I am

- a)  the owner of the small business concern identified below:  
 b)  an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: TheraSense LLC Inc.  
 ADDRESS OF CONCERN: 1311 Harbor Bay Parkway, Suite 1000  
 Alameda, California 94502

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 C.F.R. 121.801-805, and reproduced in 37 C.F.R. 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled ELECTROCHEMICAL ANALYTE SENSOR by inventor(s) James Say, Michael F. Tomasco, Adam Heller, Yoram Gal, Behrad Aria, Ephraim Heller, Phillip John Plante and Mark S. Vreeke, described in

- a)  the specification filed herewith.  
 b)  provisional application serial no. \_\_\_, filed \_\_\_\_\_.  
 c)  non-provisional application serial no. 09/034,372, filed March 4, 1998.  
 d)  patent no. \_\_\_, issued \_\_\_\_\_.  
 U

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below\* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 C.F.R. 1.9(c) or by any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e). \*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 C.F.R. 1.27)

NAME: E. Heller & Company

ADDRESS: 1311 Harbor Bay Parkway, Suite 1000, Alameda, CA 94502

- a)  INDIVIDUAL      b)  SMALL BUSINESS CONCERN      c)  NONPROFIT ORGANIZATION

NAME: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

- a)  INDIVIDUAL      b)  SMALL BUSINESS CONCERN      c)  NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereof, or any patent to which this verified statement is directed.

NAME: \_\_\_\_\_

TITLE: \_\_\_\_\_

ADDRESS: 1311 Harbor Bay Parkway, Suite 1000, Alameda, California 94502

SIGNATURE: \_\_\_\_\_

Date: \_\_\_\_\_

*Ephraim Heller*  
4/15/98

*HJ*  
SMALL BUSINESS

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS  
C.F.R. 1.9(f) AND 1.27(c)) - SMALL BUSINESS CONCERN**

I hereby declare that I am

- a)  the owner of the small business concern identified below:  
 b)  an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: E. Heller & Company  
 ADDRESS OF CONCERN: 1311 Harbor Bay Parkway, Suite 1000  
 Alameda, California 94502

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 C.F.R. 121.801-805, and reproduced in 37 C.F.R. 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled ELECTROCHEMICAL ANALYTE SENSOR by inventor(s) James Say, Michael F. Tomasco, Adam Heller, Yoram Gal, Behrad Aria, Ephraim Heller, Phillip John Plante and Mark S. Vreeke, described in

- a)  the specification filed herewith.  
 b)  provisional application serial no. \_\_\_, filed \_\_\_\_\_.  
 c)  non-provisional application serial no. 09/034,372, filed March 4, 1998.  
 d)  patent no. \_\_\_, issued \_\_\_\_\_.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below\* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 C.F.R. 1.9(c) or by any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e). \*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 C.F.R. 1.27)

NAME: TheraSense LLC

ADDRESS: 1311 Harbor Bay Parkway, Suite 1000, Alameda, CA 94502

- a)  INDIVIDUAL      b)  SMALL BUSINESS CONCERN      c)  NONPROFIT ORGANIZATION

NAME: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

- a)  INDIVIDUAL      b)  SMALL BUSINESS CONCERN      c)  NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereof, or any patent to which this verified statement is directed.

NAME: \_\_\_\_\_

*Ephraim Heller*

TITLE: \_\_\_\_\_

*President*

ADDRESS: \_\_\_\_\_

1311 Harbor Bay Parkway, Suite 1000, Alameda, California 94502

SIGNATURE: \_\_\_\_\_

*Ephraim Heller*

Date: \_\_\_\_\_

*4/15/98*

## United States Patent Application

## COMBINED DECLARATION AND POWER OF ATTORNEY

As a below-named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:  
ELECTROCHEMICAL ANALYTE SENSOR

The specification of which

- a.  is attached hereto
- b.  is entitled ELECTROCHEMICAL ANALYTE SENSOR, having an attorney docket number of 12008.20US01.
- c.  was filed on March 4, 1998 as application serial no. 09/034,372 and was amended on (if applicable) (in the case of a PCT-filed application) described and claimed in international no. filed and as amended on (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (attached hereto).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

- a.  no such applications have been filed.
- b.  such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC § 119			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)
ALL FOREIGN APPLICATION(S), IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)

I hereby claim the benefit under Title 35, United States Code, § 120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. APPLICATION NUMBER	DATE OF FILING (day, month, year)	STATUS (patented, pending, abandoned)

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

U.S. PROVISIONAL APPLICATION NUMBER	DATE OF FILING (Day, Month, Year)

I hereby appoint the following attorney(s) or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Albrecht, John W.	Reg. No. 40,481	Lasky, Michael B.	Reg. No. 29,555
Ansems, Gregory M.	Reg. No. P-42,264	Lindquist, Timothy A.	Reg. No. 40,701
Batzli, Brian H.	Reg. No. 32,960	Lynch, David W.	Reg. No. 36,204
Beard, John L.	Reg. No. 27,612	Mau, Michael L.	Reg. No. 30,087
Berman, Charles	Reg. No. 29,249	Maunu, Leroy D.	Reg. No. 35,274
Black, Bruce E.	Reg. No. P-41,622	McDaniel, Karen D.	Reg. No. 37,674
Bogucki, Raymond A.	Reg. No. 17,426	McDonald, Daniel W.	Reg. No. 32,044
Bruess, Steven C.	Reg. No. 34,130	McIntyre, Iain A.	Reg. No. 40,377
Byrne, Linda M.	Reg. No. 32,404	Mueller, Douglas P.	Reg. No. 30,300
Canady, Karen S.	Reg. No. 39,927	Nasiedlak, Tyler L.	Reg. No. 40,099
Carlson, Alan G.	Reg. No. 25,959	Nelson, Albin J.	Reg. No. 28,650
Carter, Charles G.	Reg. No. 35,093	Orler, Anthony J.	Reg. No. 41,232
Caspers, Philip P.	Reg. No. 33,227	Pauly, Daniel M.	Reg. No. 40,123
Chiapetta, James R.	Reg. No. 39,634	Plunkett, Theodore	Reg. No. 37,209
Clifford, John A.	Reg. No. 30,247	Pytel, Melissa J.	Reg. No. P-41,512
Cooper, Victor G.	Reg. No. 39,641	Reich, John C.	Reg. No. 37,703
Crawford, Robert	Reg. No. 32,122	Reiland, Earl D.	Reg. No. 25,767
Daignault, Ronald A.	Reg. No. 25,968	Rittmaster, Ted R.	Reg. No. 32,933
Daley, Dennis R.	Reg. No. 34,994	Schmaltz, David G.	Reg. No. 39,828
Dalglish, Leslie E.	Reg. No. 40,579	Schmidt, Cecil C.	Reg. No. 20,566
Daulton, Julie R.	Reg. No. 36,414	Schuman, Mark D.	Reg. No. 31,197
DeVries Smith, Kate	Reg. No. P-42,157	Schumann, Michael D.	Reg. No. 30,422
DiPietro, Mark J.	Reg. No. 28,707	Sebald, Gregory A.	Reg. No. 33,280
Edell, Robert T.	Reg. No. 20,187	Sharp, Janice A.	Reg. No. 34,051
Epp Ryan, Sandra	Reg. No. 39,667	Skoog, Mark T.	Reg. No. 40,178
Farber, Michael B.	Reg. No. 32,612	Smith, Jerome R.	Reg. No. 35,684
Funk, Steven R.	Reg. No. 37,830	Soderberg, Richard	Reg. No. -P-43,352
Glance, Robert J.	Reg. No. 40,620	Sumner, John P.	Reg. No. 29,114
Golla, Charles E.	Reg. No. 26,896	Summers, John S.	Reg. No. 24,216
Gorman, Alan G.	Reg. No. 38,472	Tellekson, David K.	Reg. No. 32,314
Gould, John D.	Reg. No. 18,223	Trembath, Jon R.	Reg. No. 38,344
Gregson, Richard	Reg. No. P-41,804	Underhill, Albert L.	Reg. No. 27,403
Gressens, John J.	Reg. No. 33,112	Vandenburgh, J. Derek	Reg. No. 32,179
Hamre, Curtis B.	Reg. No. 29,165	Victor, David W.	Reg. No. 39,867
Hillson, Randall A.	Reg. No. 31,838	Welter, Paul A.	Reg. No. 20,890
Johnston, Scott W.	Reg. No. 39,721	Whipps, Brian	Reg. No. P-43,261
Kastelic, Joseph M.	Reg. No. 37,160	Williams, Douglas J.	Reg. No. 27,054
Kettelberger, Denise	Reg. No. 33,924	Witt McDonald, Jonelle	Reg. No. P-41,980
Komanduri, Janaki	Reg. No. 40,684	Wood, Gregory B.	Reg. No. 28,133
Kowalchyk, Alan W.	Reg. No. 31,535	Wood, William J.	Reg. No. P-42,236
Kowalchyk, Katherine M.	Reg. No. 36,848	Xu, Min S.	Reg. No. 39,536
Lacy, Paul E.	Reg. No. 38,946		
Larson, James A.	Reg. No. 40,443		

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/ organization who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Merchant, Gould, Smith, Edell, Welter & Schmidt to the contrary.

Please direct all correspondence in this case to Merchant, Gould, Smith, Edell, Welter & Schmidt at the address indicated below:

Merchant, Gould, Smith, Edell,  
Welter & Schmidt  
3100 Norwest Center  
90 South Seventh Street  
Minneapolis, MN 55402-4131

I hereby declare that all statements made ~~to~~ <sup>on</sup> my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2	Full Name Of Inventor	Family Name SAY	First Given Name James	Second Given Name
0	Residence & Citizenship	City Alameda	State or Foreign Country California	Country of Citizenship U.S.A.
1	Post Office Address	Post Office Address 460 Cola Ballena #A	City Alameda	State & Zip Code/Country CA/94501/USA
Signature of Inventor 201:			Date:	
2	Full Name Of Inventor	Family Name TOMASCO	First Given Name Michael	Second Given Name F.
0	Residence & Citizenship	City Cupertino	State or Foreign Country California	Country of Citizenship U.S.A.
2	Post Office Address	Post Office Address 22528 Poppy Drive	City Cupertino	State & Zip Code/Country CA/95014/USA
Signature of Inventor 202:			Date:	
2	Full Name Of Inventor	Family Name HELLER	First Given Name Adam	Second Given Name
0	Residence & Citizenship	City Austin	State or Foreign Country Texas	Country of Citizenship U.S.A.
3	Post Office Address	Post Office Address 5317 Valburn Circle	City Austin	State & Zip Code/Country TX/78731/USA
Signature of Inventor 203:			Date:	
2	Full Name Of Inventor	Family Name GAL	First Given Name Yoram	Second Given Name
0	Residence & Citizenship	City Kibbutz Yagur	State or Foreign Country ISRAEL	Country of Citizenship ISRAEL
4	Post Office Address	Post Office Address P. O. Box 126	City Kibbutz Yagur, 30065	State & Zip Code/Country ISRAEL
Signature of Inventor 204:			Date: <i>27 Apr 98</i>	
2	Full Name Of Inventor	Family Name ARIA	First Given Name Behrad	Second Given Name
0	Residence & Citizenship	City Alameda	State or Foreign Country California	Country of Citizenship U.S.A.
5	Post Office Address	Post Office Address 817 Santa Clara Avenue	City Alameda	State & Zip Code/Country CA/94502/USA
Signature of Inventor 205:			Date:	

I hereby declare that all statements made ~~to~~ of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2	Full Name Of Inventor	Family Name SAY	First Given Name JAMES	Second Given Name
0	Residence & Citizenship	City ALAMEDA	State or Foreign Country CALIFORNIA	Country of Citizenship USA
1	Post Office Address	Post Office Address 460 COLA BALLENA #A	City ALAMEDA	State & Zip Code/Country CALIFORNIA 94501/USA

Signature of Inventor 201:

Date:

*15 April 1998*

2	Full Name Of Inventor	Family Name TOMASCO	First Given Name MICHAEL	Second Given Name F.
0	Residence & Citizenship	City CUPERTINO	State or Foreign Country CALIFORNIA	Country of Citizenship USA
2	Post Office Address	Post Office Address 22528 POPPY DRIVE	City CUPERTINO	State & Zip Code/Country CALIFORNIA 94014/USA

Signature of Inventor 202:

Date:

*15 April 1998*

2	Full Name Of Inventor	Family Name HELLER	First Given Name ADAM	Second Given Name
0	Residence & Citizenship	City AUSTIN	State or Foreign Country TEXAS	Country of Citizenship USA
3	Post Office Address	Post Office Address 5317 VALBURN CIRCLE	City AUSTIN	State & Zip Code/Country TEXAS 78731/USA

Signature of Inventor 203:

Date:

*April 21, 98*

2	Full Name Of Inventor	Family Name GAL	First Given Name YORAM	Second Given Name
0	Residence & Citizenship	City KIBBUTZ YAGUR	State or Foreign Country ISRAEL	Country of Citizenship ISRAEL
4	Post Office Address	Post Office Address P.O. BOX 126	City KIBBUTZ YAGUR, 30065	State & Zip Code/Country ISRAEL

Signature of Inventor 204:

Date:

2	Full Name Of Inventor	Family Name ARIA	First Given Name BEHRAD	Second Given Name
0	Residence & Citizenship	City ALAMEDA	State or Foreign Country CALIFORNIA	Country of Citizenship USA
5	Post Office Address	Post Office Address 817 SANTA CLARA AVENUE	City ALAMEDA	State & Zip Code/Country CALIFORNIA 94502

Signature of Inventor 205:

Date:

*April 15 1998*

2	Full Name Of Inventor	Family Name HELLER	First Given Name EPHRAIM	Second Given Name
0	Residence & Citizenship	City OAKLAND	State or Foreign Country CALIFORNIA	Country of Citizenship USA
6	Post Office Address	Post Office Address 8101 SKYLINE BOULEVARD	City OAKLAND	State & Zip Code/Country CALIFORNIA 94611/USA
Signature of Inventor 206: <i>E.S. Heller</i>			Date: 4/15/98	
2	Full Name Of Inventor	Family Name PLANTE	First Given Name PHILLIP	Second Given Name JOHN
0	Residence & Citizenship	City SUNNYVALE	State or Foreign Country CALIFORNIA	Country of Citizenship USA
7	Post Office Address	Post Office Address M-116, 655 SOUTH FAIR OAKS AVENUE	City SUNNYVALE	State & Zip Code/Country CALIFORNIA 94086/USA
Signature of Inventor 207: <i>Phillip J. Plante</i>			Date: 4/15/98	
2	Full Name Of Inventor	Family Name VREEKE	First Given Name MARK	Second Given Name S.
0	Residence & Citizenship	City ALAMEDA	State or Foreign Country CALIFORNIA	Country of Citizenship USA
5	Post Office Address	Post Office Address 2826 CALHOUN STREET	City ALAMEDA	State & Zip Code/Country CALIFORNIA 94501/USA
Signature of Inventor 208: <i>Mark Vreeke</i>			Date: 4/15/98	

**§ 1.56 Duty to disclose information material to patentability.**

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim;
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
  - (i) Opposing an argument of unpatentability relied on by the Office, or
  - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

- (c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:
  - (1) Each inventor named in the application;
  - (2) Each attorney or agent who prepares or prosecutes the application; and
  - (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.
- (d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.